

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IN2004/000352

International filing date (day/month/year)
16.11.2004

Priority date (day/month/year)
11.02.2004

International Patent Classification (IPC) or both national classification and IPC
C07D401/04, A61K31/505

Applicant
NATCO PHARMA LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IN2004/000352

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/N2004/000352

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-6

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims _____
	No: Claims _____ 1-6
Inventive step (IS)	Yes: Claims _____
	No: Claims _____ 1-6
Industrial applicability (IA)	Yes: Claims — (1-6)
	No: Claims _____

2. Citations and explanations

see separate sheet

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IN2004/000352

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and /or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

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1. From the state of the art as represented by the documents cited in the International Search Report and acknowledged in the specification of the present application polymorphs α and β of imatinib mesylate are known.

Claims 1 to 6 of the present application are directed to another, allegedly **new** polymorph, α_2 , of imatinib mesylate, a process for its production and the use thereof.

Claim 7 relates to the solution of a different technical problem, i.e, the provision of another process for the production of the **known** β polymorph of imatinib mesylate.

Therefore it is considered that polymorph α_2 , its use and production and the process for the production of the known polymorph β , respectively, are not linked by a single inventive concept and that the application therefore lacks unity of invention (Rule 13 PCT). The present written opinion will deal with the subject-matter first mentioned in Claims 1 to 6.

The International Search Report has been drawn up in respect of the entire international application but the international preliminary examining authority is of the opinion that the application does not comply with the requirements of unity of invention as set forth in the PCT regulations (Article 34 (3), Rule 68 (1) PCT) for the reasons set out above. Hence, the Applicant may want to restrict the claims. If they were restricted to those dealing with any one of the above identified inventions/groups of inventions, they would then comply with the requirements of unity of invention.

Alternatively, as a full search report has been established, a full preliminary examination may also be conducted, providing that additional preliminary examination fees are paid (Article 34 (3) (a), Rule 68 (2) PCT).

2. The priority documents pertaining to the present application were not available at the time of establishing the first written opinion. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct document D1: WO 2004/106326 A (HETERO DRUGS LTD.) 9 December 2004 (2004-12-09), cited in the International Search Report could become relevant in order to assess whether the claims satisfy the criteria set forth in Article 33 (1) PCT.

3. With regard to the close similarity of the X-ray powder diffraction data provided in the application and the closest prior art, D2: WO 99/03854 A (NOVARTIS AG) 28 January 1999 (1999-01-28), the claimed polymorph is considered not to be novel vis-à-vis this prior art (Art. 33 (2) PCT).

Regarding inventive step it is noted that alleged advantages to which the applicant merely refers (page 22) without offering sufficient evidence to support the comparison with the closest prior art cannot be taken into consideration in determining the problem underlying the invention and therefore in assessing inventive step (Art. 33 (3) PCT).